

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE ORPHAN THERAPIES LLC and
SANOFI-AVENTIS DEUTSCHLAND
GMBH,

Plaintiffs,

v.

FRESENIUS KABI USA, LLC,

Defendant.

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C.A. No. _____

COMPLAINT

Plaintiffs Shire Orphan Therapies LLC and Sanofi-Aventis Deutschland GmbH (collectively “Plaintiffs”), by their undersigned attorneys, for their Complaint against defendant Fresenius Kabi USA, LLC (“Fresenius Kabi” or “Defendant”) herein allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 5,648,333 (“the ’333 patent”), attached hereto as Exhibit A.

THE PARTIES

2. Plaintiff Shire Orphan Therapies LLC is a limited-liability company organized and existing under the laws of Delaware, and its principal place of business is located at 300 Shire Way, Lexington, Massachusetts 02421. Shire Orphan Therapies LLC was formerly known as Shire Orphan Therapies, Inc.

3. Plaintiff Sanofi-Aventis Deutschland GmbH is a company organized and existing under the laws of Germany, and its principal place of business is located at Brüningstrasse 50, D-65926, Frankfurt am Main, Germany.

4. Upon information and belief, Defendant Fresenius Kabi is a limited-liability company organized and existing under the laws of the State of Delaware, and its principal place of business is located at Three Corporate Drive, Lake Zurich, Illinois 60047.

5. Upon information and belief, Fresenius Kabi is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including throughout the State of Delaware.

JURISDICTION AND VENUE

6. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Fresenius Kabi because, *inter alia*, Fresenius Kabi is a company organized under the laws of the State of Delaware and Fresenius Kabi has a registered agent for service of process in Delaware. This Court therefore has general personal jurisdiction over Fresenius Kabi.

8. This Court also has personal jurisdiction over Fresenius Kabi because, *inter alia*, upon information and belief, Fresenius Kabi: (1) holds an active pharmacy wholesale license for the State Delaware under License No. A4-0000901 and an active distributor/manufacture license for controlled substances for the State of Delaware under License No. DM-0006436; (2) has previously submitted to the jurisdiction of this Court and has availed itself of the legal protection of the State of Delaware, having consented to jurisdiction in this Court, *see, e.g., Astellas Pharma Inc. et al. v. Fresenius Kabi USA LLC*, 1:15-cv-00080-LPS (D. Del. Jan. 23, 2015); *Cephalon, Inc. v. Fresenius Kabi USA, LLC*, 1:15-cv-536-LPS (D. Del. June 24, 2015); *Cubist Pharmaceuticals Inc. v. Fresenius Kabi USA LLC*, 1:14-cv-00914-GMS (D. Del. July 11, 2014); *Allos Therapeutics Inc. et al. v. Teva Pharmaceuticals USA Inc. et al.*, 1:14-cv-00778-RGA (D. Del. June 19, 2014); *Celgene Corporation et al. v. Fresenius Kabi USA LLC et al.*,

1:14-cv-00571-RGA (D. Del. Apr. 30, 2014); *Pfizer Inc. et al. v. Fresenius Kabi USA LLC*, 1:13-cv-01893-SLR (D. Del. Nov. 13, 2013); *Millenium Pharmaceuticals Inc. v. Fresenius Kabi USA LLC et al.*, 1:13-cv-00467-GMS (D. Del. Mar. 22, 2013); *Fresenius Kabi USA LLC v. Claris Lifesciences Ltd. et al.*, 1:14-cv-01498-RGA (D. Del. Dec. 19, 2014); *Fresenius Kabi USA LLC v. Mylan Laboratories Limited et al.*, 1:14-cv-01438-RGA (D. Del. Nov. 26, 2014); *Fresenius Kabi USA LLC v. Dr. Reddy's Laboratories Ltd et al.*, 1:14-cv-00160-RGA (D. Del. Feb. 6, 2014); *Fresenius Kabi USA LLC v. Watson Laboratories Inc. et al.*, 1:14-cv-00161-RGA (D. Del. Feb. 6, 2014); and (3) maintains extensive systematic contacts within the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents.

9. This Court also has personal jurisdiction over Fresenius Kabi because, *inter alia*, Fresenius Kabi has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Shire Orphan Therapies LLC, a Delaware limited-liability company. Fresenius Kabi prepared, submitted, and filed with the United States Food and Drug Administration (“FDA”), pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (codified at 21 U.S.C. § 355(j)), Abbreviated New Drug Application (“ANDA”) No. 208317 (“ANDA No. 208317”) seeking approval to engage in the commercial manufacture, use, and/or sale of Icatibant Injection, 10 mg/mL, 3 mL filled syringes (“Fresenius Kabi’s ANDA Product”) before the expiration of the ’333 patent throughout the United States, including in this judicial district.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

BACKGROUND FACTS

11. Shire Orphan Therapies LLC owns New Drug Application (“NDA”) No. 022150 for icatibant acetate, which was approved on August 25, 2011 and is marketed under the name FIRAZYR®. FIRAZYR is sold as a single-use, prefilled syringe for subcutaneous administration, each prefilled syringe delivering 3 mL of a solution equivalent to a 30 mg icatibant (free base) dose.

12. FIRAZYR (icatibant) is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

13. The ’333 patent, entitled “Peptides Having Bradykinin Antagonist Action,” was duly and legally issued by the United States Patent and Trademark Office on July 15, 1997. Sanofi-Aventis Deutschland GmbH owns the ’333 patent. Shire Orphan Therapies LLC is the exclusive licensee of the ’333 patent.

14. Pursuant to 21 U.S.C. § 355(b)(1), the ’333 patent is listed in the FDA’s publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “*Orange Book*”) as covering FIRAZYR.

15. Fresenius Kabi prepared, submitted, and filed ANDA No. 208317 under § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)), seeking approval from the FDA to engage in the commercial manufacture, use, or sale of icatibant. Fresenius Kabi included in ANDA No. 208317 a “paragraph IV” certification seeking such approval before the expiration of the ’333 patent. And upon information and belief, upon approval of ANDA No. 208317, Fresenius Kabi will be involved, directly and/or indirectly, in the manufacture, use, sale, offer for sale, and/or importation of Fresenius Kabi’s ANDA Product.

16. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification “include a detailed statement of

the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(6) requires that such a letter include “[a] detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement must include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.” 21 C.F.R. § 314.95(c)(6)(i)-(ii).

17. Plaintiffs received a letter dated October 27, 2015 that was purportedly sent pursuant to § 505(j)(2)(B)(ii) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(ii) regarding Fresenius Kabi’s ANDA Product and the ’333 patent (the “October 27 Notice Letter”).

18. The October 27 Notice Letter does not include any non-infringement contentions with respect to claims 1, 4-6, 10, 11, 13, 14, 25, and 27 of the ’333 patent.

19. The October 27 Notice Letter does not include any invalidity or unenforceability contentions with respect to claims 2, 7-9, 12, 15-19, 21-24, 26, and 28-33 of the ’333 patent.

20. The October 27 Notice Letter included an Offer of Confidential Access (“OCA”) purportedly pursuant to 21 U.S.C. § 355(j)(5)(C). Plaintiffs objected to certain provisions of Fresenius Kabi’s OCA as unreasonable and in violation of 21 U.S.C. § 355(j)(5)(C)(i)(III). By way of example only, Fresenius Kabi’s OCA contains FDA and patent prosecution bars, even though no facts have been provided to show that there is good cause to impose such bars.

CLAIM FOR RELIEF
(Infringement of the ’333 Patent)

21. Plaintiffs repeat and re-allege each of the foregoing Paragraphs as if fully set forth herein.

22. Upon information and belief, Fresenius Kabi has submitted ANDA No. 208317 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Fresenius Kabi's ANDA Product—a product claimed and the use of which is claimed in the '333 patent—before the expiration of the '333 patent.

23. Upon information and belief, Fresenius Kabi included in ANDA No. 208317 a paragraph IV certification in an attempt to obtain approval to engage in the commercial manufacture, use, or sale of Fresenius Kabi's ANDA Product before the expiration of the '333 patent.

24. Upon information and belief, Fresenius Kabi will commercially manufacture, use, sell, offer for sale, and/or import its ANDA Product upon, or in anticipation of, FDA approval.

25. The submission of ANDA No. 208317 with a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Fresenius Kabi's ANDA Product before the expiration of the '333 patent was an act of infringement by Fresenius Kabi—directly and/or indirectly—of one or more claims of the '333 patent under 35 U.S.C. § 271(e)(2).

26. Upon information and belief, Fresenius Kabi's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Fresenius Kabi's ANDA Product that is the subject of ANDA No. 208317 would infringe, directly and/or indirectly (including by inducement and/or contributory infringement), one or more claims of the '333 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

27. Upon information and belief, the sale or offer for sale of Fresenius Kabi's ANDA Product by Fresenius Kabi would induce and/or contribute to third party infringement of one or more claims of the '333 patent under 35 U.S.C. § 271.

28. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States Fresenius Kabi's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Fresenius Kabi will encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the use of which infringes the claims, of the '333 patent. Upon information and belief, Fresenius Kabi intends such inducement by third parties, as it is in the business of developing, manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, Fresenius Kabi knows that its actions will induce direct infringement of claims of the '333 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

29. Upon information and belief, by offering for sale or selling within the United States or importing into the United States Fresenius Kabi's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, Fresenius Kabi will contribute to infringement of claims of the '333 patent by third parties because: (i) Fresenius Kabi's ANDA Product constitutes a material part of the methods of treatment claimed in the '333 patent; (ii) Fresenius Kabi knows or should know that Fresenius Kabi's ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the '333 patent; and (iii) Fresenius Kabi's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

30. Fresenius Kabi's infringement of the '333 patent will cause Plaintiffs to suffer irreparable harm. Fresenius Kabi's infringement will continue unless enjoined by the Court.

Plaintiffs have no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Fresenius Kabi from infringing the '333 patent.

31. At least as of the date of the October 27 Notice Letter, Fresenius Kabi was aware of the existence of the '333 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not infringe one or more claims of the '333 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 208317 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of Fresenius Kabi's ANDA Product—a product (1) that is claimed in the '333 patent and (2) whose use is claimed in the '333 patent—before the expiration of the '333 patent—constitutes an act of infringement of the '333 patent by Fresenius Kabi;

B. A Judgment declaring that, pursuant to 35 U.S.C. § 271(a), (b), and (c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Fresenius Kabi's ANDA Product before the expiration of the '333 patent will constitute an act of direct infringement and/or indirect infringement, including by inducement and/or contributory infringement of the '333 patent, by Fresenius Kabi;

C. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), the effective date of any approval of Fresenius Kabi's ANDA Product shall be no earlier than the date on which the '333 patent expires, including any regulatory extensions;

D. Injunctive relief pursuant to 35 U.S.C. §§ 271(e)(4)(B) precluding Fresenius Kabi from manufacturing, using selling, offering to sell, or importing Fresenius Kabi's ANDA Product prior to the date on which the '333 patent has expired, including any regulatory extensions;

E. A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Plaintiffs their attorneys' fees;

F. A Judgment awarding Plaintiffs their costs under Fed. R. Civ. P. 54(d) and 28 U.S.C. § 1920; and

G. Such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com

OF COUNSEL:

Edgar H. Haug
Sandra Kuzmich, Ph.D.
Laura A. Fanelli
Ying-Zi Yang, Ph.D.
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151

Attorneys for Plaintiffs

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